Filed on behalf of: Par Pharmaceutical, Inc.

Entered: May 18, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.
Petitioner

v.

NOVARTIS AG
Patent Owner

Case IPR2016-01479
U.S. Patent No. 9,006,224

Before LORA M. GREEN, CHRISTOPHER L. CRUMBLEY, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

PETITIONER'S OBJECTIONS TO PATENT OWNER'S EVIDENCE

Under 37 C.F.R. § 42.64(b)(1), Petitioner Par Pharmaceutical, Inc. ("Petitioner") submits the following objections to evidence filed by Patent Owner Novartis AG ("Patent Owner") on May 11, 2017. Petitioner's objections apply equally to Patent Owner's reliance on this evidence in any subsequently-filed documents or further proceedings in this matter. These objections are timely, having been filed and served within five business days of Patent Owner's Response (Paper 17) and accompanying exhibits in this proceeding.

Notwithstanding these objections, Petitioner expressly reserves the right to rely on any evidence submitted by Patent Owner, including on the ground that such evidence constitutes a party admission.

Objections

Exhibit 2041 (Kulke Decl.)

Petitioner objects to this document as inadmissible hearsay under FRE 801 and 802 that does not fall under any exceptions, including those of FRE 803, 804, 805, or 807, and as improper expert testimony under FRE 702, 703, and 37 C.F.R. § 42.65, to the extent it impermissibly acts as a conduit for hearsay, including the hearsay objected to herein, and does not rely on the kinds of facts or data that experts in the relevant field would reasonably rely on in forming an opinion on the subject without providing the underlying facts, data, and other required disclosures.

Petitioner objects to this document for lack of foundation and lack of

personal knowledge, as improper expert testimony under FRE 702, 703, and 37 C.F.R. § 42.65, and as improper lay testimony under FRE 701, to the extent it offers testimony in areas outside of Dr. Kulke's area of expertise or fails to properly provide the underlying facts, data, and other required disclosures, including but not limited to the portions at paragraphs 229-239. The declarant is not stated to have expertise with respect to organic or medicinal chemistry or pharmacology.

Exhibit 2054 (FDA Guidance)

Petitioner objects to this document under FRE 401 and 402, as the document does not have a tendency to make the facts for which it is offered any more or less probable than those facts would otherwise be.

Petitioner objects to this document under FRE 403, as any probative value is substantially outweighed by a danger of unfair prejudice, confusing the issues, wasting time, and needlessly presenting cumulative evidence.

To the extent Patent Owner relies on the contents of this exhibit for the truth asserted, Petitioner objects to this document as inadmissible hearsay under FRE 801 and 802 that does not fall under any exceptions, including FRE 803, 804, 805, or 807.

Exhibit 2097 (Wyeth Press Release)

Petitioner objects to this document under FRE 401 and 402, as the document

does not have a tendency to make the facts for which it is offered any more or less probable than those facts would otherwise be.

Petitioner objects to this document under FRE 403, as any probative value is substantially outweighed by a danger of unfair prejudice, confusing the issues, wasting time, and needlessly presenting cumulative evidence.

To the extent Patent Owner relies on the contents of this exhibit for the truth asserted, Petitioner objects to this document as inadmissible hearsay under FRE 801 and 802 that does not fall under any exceptions, including FRE 803, 804, 805, or 807.

Petitioner objects to this document as not properly authenticated under FRE 901 because Patent Owner has not presented any evidence that the document is authentic nor that the document is self-authenticating under FRE 902.

Exhibits 2044 (Afinitor® Supp. Approval Letter), 2056 (Hidalgo 2006), 2068 (2013 PDR), 2073 (2016 PDR), 2081 (Sandostatin (octreotide) Approval History), 2089 (Sutent® FDA Suppl. Approval Letter), 2098 (Zanosar® (streptozocin) Approval History), 2101 (Eisen), 2102 (Pacey), 2103 (Ratain 2006)

Petitioner objects to these documents under FRE 401 and 402, as the documents do not have a tendency to make the facts for which it is offered any more or less probable than those facts would otherwise be.

Petitioner objects to these documents under FRE 403, as any probative value is substantially outweighed by a danger of unfair prejudice, confusing the issues,

wasting time, and needlessly presenting cumulative evidence.

To the extent Patent Owner relies on the contents of these exhibits for the truth asserted, Petitioner objects to these documents as inadmissible hearsay under FRE 801 and 802 that do not fall under any exceptions, including FRE 803, 804, 805, or 807.

Exhibits 2105 (Ratain Dep. Tr. I) and 2106 (Ratain Dep. Tr. II)

Petitioner objects to these documents as inadmissible hearsay under FRE 801 and 802 that does not fall under any exceptions, including FRE 803, 804, 805, or 807. Petitioner further objects to these documents as incomplete under FRE 106 as they only include select portions of larger documents that in fairness ought to be considered in connection with these exhibits.

Respectfully submitted,

Dated: May 18, 2017

By: /Daniel G. Brown/

Daniel G. Brown (Reg. No. 54,005)
daniel.brown@lw.com
Latham & Watkins LLP
885 Third Avenue
New York, NY 10022-4834
212.906.1200; 212.751.4864 (Fax)

Counsel for Petitioner Par Pharmaceutical, Inc.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.